REMARKS

Claims 4, 5, 10 and 28-32 are pending the application; Claims 4, 5, 10 and 28-32 stand rejected.

Claims 4-5,10 and 28-32 stand rejected under 35 USC §112 as allegedly failing to comply with the written description requirement. Applicant respectfully traverses these rejections. The Examiner cites that the phrase "water that is not boiling" does not appear literally in the specification; what does appear in Example 1 is, "extracted in 1 ml of distilled water". Persons skilled in the art would take this statement in the context of its attendant disclosure to mean that the water was not boiling, else it would have been so specified. Claim language does not require a literal antecedent in the specification; a writing which, when read by a person of skill in the art, together with the context of the rest of the disclosure, is sufficient to impart the claimed expression is sufficient. The Examiner also cites that the phrase, "such that it is the therapeutic amount of the substance administered that treats or disrupts the amyloid fibrils" is also not literally present. In addition to the argument presented above, it is also the case that inferences that may be fairly made by persons skilled in the art from what is written in the disclosure are also adequate support for claimed expressions. In this case, the entire thrust of the disclosure is directed to amyloid inhibition by the therapeutic amount of substance administered. The claims are believed therefore to be in compliance with the stated requirement and reconsideration is requested.

Claims 4-5, 10 and 28-32 stand rejected under 35 USC §102 as allegedly anticipated by JP 10245342 (Mitsui Norin) or by JP 10-175858 (Takami); Applicant respectfully traverses these rejections. The claims require selection of a therapeutic substance that can only be either green tea, green tea leaves or green tea extract, and none of the claims require the use of epicatechin. In addition, Claim 10 depends from claim 4 and properly construed contains all the limitation of claim 4, and is therefore not anticipated either; moreover, claim 10 further requires the presence

of at least one of the substances, ginkgo biloba, rosemary, gotu kola, bacopin or ginseng, and Independent claim 4 and all new claims all now require either green tea, green tea leaves or green tea extract. Mitsui Norin makes no mention of fibril formation at all (see argument below). Mitsui Norin only teaches narrowly that a certain kind of nerve cell toxicity that is supposedly caused by beta-amyloid protein, can possibly be reduced with tea polyphenols.

Takami also makes no mention of fibril formation at all (see argument below). Takami only teaches narrowly that a certain kind of active oxygen toxicity can be reduced by disclosed extracts of green tea containing various catechins. Nothing beyond a passing reference is said about Alzheimer's disease, and certainly nothing about treating amyloid fibrils.

There are thus no necessary inferences to be drawn from the cited studies pertaining to neuronal cell death or active oxygen reduction as to Aß fibrillogenesis, because in at least some of the reported studies, the causes of the cell death do not involve any effect on Aß fibrillogenesis. There is thus no implication available to serve as a teaching that inhibition of nerve cell death or nerve cell toxicity by Aß inherently leads to treating Aß fibril formation, deposition, accumulation and/or persistence.

Therefore none of the claims inherently read on any of teaching of the cited references. Applicant respectfully submits that the cited doctrine of inherency therefore does not apply to the rejected method claims.

The Examiner is also respectfully directed again to review the following Federal Circuit authority on the subject of inherency. This reviewing court which sets the law to which both Applicant and the PTO must adhere, has already determined that some kinds of apparent "inherency" do not justify a rejection of claims. *In re Randall Wright*, 848 F.2d 1216, 6 USPQ2d 1959 (Fed.Cir. 1988). The Court says all cases must be decided on their own facts, and goes on

to say, while reversing a PTO inherency rejection of claims not unlike the one presented in this application,

> Thus the question is whether what the inventor did would have been obvious to one of ordinary skill in the art attempting to solve the problem upon which the inventor was working. *Rinehart*, 531 F.2d at 1054, 189 USPQ at 149; see also *In re Benno*, 768 F.2d 1340, 1346, 226 USPQ 683, 687 (Fed.Cir. 1985) ("appellant's problem" and the prior art "present different problems requiring different solutions").
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> The problem upon which Wright was working was improving the pitch-measuring capability of the level, not the visibility of the bubble. The PTO, having conceded that Wright's structure was unobvious for his intended purpose, erred in holding that this was not relevant. The problem solved by the invention is always relevant. The entirety of a claimed invention, including the combination viewed as a whole, the elements thereof, and the properties and purpose of the invention, must be considered. [Emphasis added]

Wright, 848 F.2d at 1219. Just as in the *Rinehart* and *Wright* cases above, so also in this case, "[Applicant's] problem and the prior art present different problems requiring different solutions". It has to be relevant that the problem solved by Applicant (treatment of amyloid fibrils) is not the problem addressed by the cited references (nerve cell toxicity and cell death). Under the law of the Federal Circuit, which is the law the binds the PTO, the rejected claims are therefore not "inherently" present in the cited references, and they therefore must be allowed over the cited art.

The specific limitations of the rejected claims must therefore all be read in any attempt to read any of the claims upon any prior art methods, and the claimed methods, especially as now amended, all differ markedly from the teachings of the cited references. The Examiner asserts that the cited references teach the same method steps that are claimed in this case, but that is not so. The rejected claims are directed to

It is also the case that, in the claimed method steps, the step of administering a therapeutic amount (or a therapeutically effective amount) of a selected substance alone is a step that is different from any implied step in any of the cited references, since whatever amount might be

therapeutic in treating cell death or neurotoxicity (as taught by Mitsui Norin), or active oxygen (as taught by Takami), is not necessarily therapeutic for any of the amyloid fibrillogenesis involved in the therapeutic targets of the rejected claims. (See again Snow Declaration, and the *Wright* case.)

Claims 4, 5, 10 and 28-32 are also rejected under 35 USC 103 over Mitsui Norin and Takami in view of Chatterjee, and the recognized state of the art; Applicant respectfully traverses these rejections as well. Again, it appears the 103 argument is only directed to claim 10, and is dealt with accordingly here. Primarily for reasons already argued above, none of the cited references, nor any combination of them, make obvious the combination of steps and substances in claim 10, as no combination of references teaches or suggests all of the steps and substances of claim 10. Claim 10 properly read contains all the limitations of Claim 4, and as such, all cited references fail to suggest the combination of steps and substances actually claimed. The rejected claims are therefore all believed to be non-obvious and allowable over the cited art, and reconsideration is requested. Applicant again traverses the Examiner's unsupported supposition that any of the listed ingredients are known in the art to be efficacious in treating amyloid fibrils; Applicant claims to have discovered this, and the Examiner cites no reference or authority to the contrary.

Amended Claim 4 recites two distinct method steps not disclosed in any cited reference:

> "the method comprising the step of treating amyloid fibril formation, deposition, accumulation, aggregation and/or persistence in Alzheimer's disease and type II diabetes ... " and
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> "such that it is the therapeutic amount of the substance administered that treats or disrupts the amyloid fibrils."

The presence of these distinct method steps alone make the cited doctrine of inherency inapplicable, because even if it could be applied in this case, it could not be applied to a claimed method where the method steps themselves are not covered in the references. In addition, Claim 4 now no longer recites epicatechin, and it no longer recites inhibition or management of fibrils, which, as suggested by the Examiner, narrows the applicability of the cited references because we are not claiming the case where fibrils are not already present in the subject. For these additional reasons, Claim 4 and its dependents are all believed to be allowable and reconsideration is requested.

Claim 28 includes an express recitation that the fibrils to be treated are already existing. Claim 28 and its dependents are therefore also believed to be allowable.

Claim 31 includes the express recitation of several new process steps by which the therapeutic substances are to be derived. It is believed that these explicit process steps among others, which are novel over any process disclosed by the cited art, render the claim allowable. Claim 31 now requires that the substances to be administered be created by (1) a water extraction using water that is not boiling of one the substances selected from green tea, green tea leaves, and green tea extract, and (2) separation and lyophilization of the supernatant from the extract. These processes, which are set forth in Example 1 of the specification, are distinct from the extraction processes taught by the references. For instance, in Mitsui in paragraph 0027, the green tea extraction is only taught to proceed either by boiling water extraction or by boiling alcohol or acetone extraction. These are significantly different extraction steps and likely to produce significantly different extracts. Mitsui then teaches separation of the extract by HPLC or by organic solvent dilution. This is a different step entirely from the claimed simple separation of

supernatant and lyophilization. Accordingly, Claim 31 is neither anticipated or rendered obvious by any of the cited references, and early allowance is requested.

Applicant believes that it has responded fully to all of the concerns expressed by the Examiner in the previous Final Action, and respectfully requests reexamination of all rejected claims and early favorable action on them. If the Examiner has any further concerns, Applicant requests a call to Patrick Dwyer at (206) 343-7074.

Respectfully submitted,

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